Complaint means any expression, written or oral, indicating a potential denial of any right or protection contained in HIPAA requirements (whether ultimately justified or not) by an individual, a personal representative or other entity acting on behalf of an individual, or any entity that believes such a right is being or has been denied an individual.

Group health insurance policy or group policy means the legal document or contract issued by an issuer to a plan sponsor with respect to a group health plan (including a plan that is a non-Federal governmental plan) that contains the conditions and terms of the insurance that covers the group.

HIPAA requirements means the requirements of title XXVII of the PHS Act and its implementing regulations in parts 146 and 148 of this subchapter.

Individual health insurance policy or individual policy means the legal document or contract issued by the issuer to an individual that contains the conditions and terms of the insurance. Any association or trust arrangement that is not a group health plan as defined in §144.103 of this subchapter or does not provide coverage in connection with one or more group health plans is individual coverage subject to the requirements of part 148 of this subchapter. The term "individual health insurance policy" includes a policy that is—

- (1) Issued to an association that makes coverage available to individuals other than in connection with one or more group health plans; or
- (2) Administered, or placed in a trust, and is not sold in connection with a group health plan subject to the provisions of part 146 of this subchapter.

Plan document means the legal document that provides the terms of the plan to individuals covered under a group health plan, such as a non-Federal governmental health plan.

State law means all laws, decisions, rules, regulations, or other State action having the effect of law, of any State as defined in §144.103 of this subchapter. A law of the United States applicable to the District of Columbia is treated as a State law rather than a law of the United States.

Subpart B—CMS Enforcement Processes for Determining Whether States Are Failing To Substantially Enforce HIPAA Requirements

§150.201 State enforcement.

Except as provided in subpart C of this part, each State enforces HIPAA requirements with respect to health insurance issuers that issue, sell, renew, or offer health insurance coverage in the State.

§ 150.203 Circumstances requiring CMS enforcement.

CMS enforces HIPAA requirements to the extent warranted (as determined by CMS) in any of the following circumstances:

- (a) Notification by State. A State notifies CMS that it has not enacted legislation to enforce or that it is not otherwise enforcing HIPAA requirements.
- (b) Determination by CMS. If CMS receives or obtains information that a State may not be substantially enforcing HIPAA requirements, it may initiate the process described in this subchapter to determine whether the State is failing to substantially enforce these requirements.
- (c) Special rule for guaranteed availability in the individual market. If a State has notified CMS that it is implementing an acceptable alternative mechanism in accordance with \$148.128 of this subchapter instead of complying with the guaranteed availability requirements of \$148.120, CMS's determination focuses on the following:
- (1) Whether the State's mechanism meets the requirements for an acceptable alternative mechanism.
- (2) Whether the State is implementing the acceptable alternative mechanism.
- (d) Consequence of a State not implementing an alternative mechanism. If a State is not implementing an acceptable alternative mechanism, CMS determines whether the State is substantially enforcing the requirements of §§148.101 through 148.126 and §148.170 of this subchapter.